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Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANA LEVINE,

Respondent.

ON WRIT OF CERTIORARI
TO THE SUPREME COURT OF VERMONT

BRIEF FOR *AMICUS CURIAE* THE NATIONAL COALITION AGAINST CENSORSHIP IN SUPPORT OF RESPONDENT

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INTEREST OF THE *AMICUS*[1]

The National Coalition Against Censorship (NCAC), founded in 1974, is an alliance of 50 national nonprofit organizations, including religious, educational, professional, artistic, labor, and civil rights groups united in the conviction that freedom of thought, inquiry and expression are indispensable to a healthy democracy. Among NCAC's projects is The Knowledge Project: Censorship & Science, which educates the public and policy-makers about the importance of safeguarding the free exchange of information about scientific research and developments. The Knowledge Project advocates for greater transparency in government decision-making about science, and for the public's right to know non-classified scientific information, especially when that information implicates public health and welfare. Because the issues in this case relate to the ability of the public to receive truthful information about the risks of pharmaceuticals beyond that which is disclosed on FDA-approved labels, participation as *amicus* in this case falls squarely within NCAC's mission. The positions advocated by the NCAC in this brief do not necessarily reflect the positions of each of its participating organizations.

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[1] Petitioners and Respondents have filed blanket consents to the submission of *amicus* briefs with this Court. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, or its members, or counsel, made a monetary contribution to its preparation or submission.

INTRODUCTION

The question in this case is whether conflict preemption principles preclude imposition of liability against the defendant under state tort law. Defendant Wyeth argues that Food and Drug Administration ("FDA") regulations prevented it from issuing more robust warnings about its drug, Phenergan, than those approved by the FDA. Wyeth asserts that because it could not comply with both state law (requiring more robust warnings) and federal law (precluding more robust warnings, absent FDA approval), conflict preemption prevents imposition of state tort failure-to-warn liability.

There are a number of bases for rejecting Wyeth's contention that state tort law is preempted by FDA regulations. These include: The basic presumption against preemption; the power of a drug company pursuant to 21 C.F.R. section 314.70(c) to issue additional warnings without pre-approval by the FDA; the fact that there is no evidence in the record that the FDA considered, let alone rejected, a proposed label that would have fulfilled Wyeth's state tort duties; and others. These issues were all carefully considered by the Vermont Supreme Court in its opinion and are addressed in other principal and *amici* briefs. This brief is intended to focus on one narrow aspect of Wyeth's conflict preemption argument: Wyeth's First Amendment right (whether actually exercised or not) to provide additional truthful warnings about the risks of its product, over and above the warnings contained in the label approved by the FDA.

State police powers designed to protect citizens' health and safety afford Vermont (and every other state) the power to impose liability on manufacturers for failing to adequately warn about the dangers of their products. *Medronic v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996). Absent some impediment in federal law that otherwise ***precludes*** such a warning, there can be no federal preemption of those state police powers.

Nothing in the Food, Drugs and Cosmetics Act ("FDCA") ***precluded*** Wyeth from issuing additional warnings, even without FDA approval. *See* 21 C.F.R. section 314.70(c). But even if there were, in fact, such a statutory preclusion, it would be trumped by Wyeth's right and power under the First Amendment to issue additional truthful warnings about the risks of the "IV push" administration of Phenergan. Conflict preemption principles cannot apply in the first instance if there is no ***valid*** federal law that is in conflict with state law. Because the First Amendment gave Wyeth the ***power*** to issue additional truthful warnings, and state law imposed the ***duty*** to do so, there is no conflict between state and federal law.

LEGAL ARGUMENT

WYETH HAD THE RIGHT, UNDER THE FIRST AMENDMENT, TO PROVIDE MORE ROBUST WARNINGS AND COULD, THEREFORE, COMPLY WITH STATE LAW REQUIREMENTS THAT IT DO SO.

Wyeth's basic argument in this case (see Petitioner's Principal Brief, pp i, 12-39) is that because the FDA controls the content of pharmaceutical drug labels, including the warning information, Wyeth could not comply with both federal law (which dictated the permitted warnings) and state law (which required more robust warnings). As such, Wyeth argues, it could not comply with both federal and state law, thereby invoking conflict preemption principles to preclude application of state tort liability principles.

The fundamental problem with Wyeth's argument is its premise that it could not provide more robust warnings without violating FDA regulations against "misbranding." That assertion is patently untrue in light of Wyeth's First Amendment right to disseminate truthful statements about its product – including truthful warnings about the danger of using it as an "IV push." The drug industry agrees: The First Amendment right to provide truthful information about pharmaceuticals has long been the industry's own rallying cry for the manufacturers' right to promote the off-label use of FDA-approved drugs.

A. The First Amendment protects the right of drug companies to make truthful statements about their products.

Warnings about the risk of use of drugs is pure speech. Warnings are not given in order to enhance the sale of the product. Rather, warnings tend to limit product sales and, as such, do not fall within the ambit of "commercial" speech. Because FDA regulations applied as argued by Wyeth would be a content-based restriction on Wyeth's First Amendment right to speak, they must pass the strict scrutiny test. *United States v. Playboy Entertainment Group, Inc.*, 529 U.S. 803, 813, 120 S.Ct. 1878, 146 L.Ed.2d 865 (2000), *U.S. v. Grace*, 461 U.S. 171, 103 S.Ct. 1702, 75 L.Ed.2d 736 (1983).

But even if warnings were considered to be commercial speech, Wyeth's interpretation of FDA regulations violates the First Amendment. This Court has already held that the FDCA and FDA regulations must comport with the Free Speech Clause of the First Amendment under *Central Hudson Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 566, 100 S.Ct. 2343, 65 L.Ed.2d 341(1980). *Thompson v. Western States Medical Center*, 535 U.S. 357, 365, 122 S.Ct. 1497 (2002).

(1) More robust warnings than those contained in the FDA label constitute pure, not commercial, speech and are subject to the most extensive First Amendment protection.

Wyeth's argument that FDA regulations prohibit additional truthful warnings is a content-based restriction on speech and, as such, must meet strict scrutiny requirements. *United States v. Playboy Entertainment Group, Inc.*, 529 U.S. 803, 813, 120 S.Ct. 1878, 146 L.Ed.2d 865 (2000), *U.S. v. Grace*, 461 U.S. 171, 103 S.Ct. 1702, 75 L.Ed.2d 736 (1983).

Whether a given communication constitutes commercial speech is predicated on "the commonsense distinction between speech proposing a commercial transaction . . . and other varieties of speech." *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 64, 103 S.Ct. 2875, 77 L.Ed.2d 469 (1983). In *Bolger*, this Court identified three factors to use in determining whether speech is "pure" speech or commercial speech: (1) Whether the speech is concededly an advertisement; (2) Whether the speech refers to a specific product; and, (3) Whether the speaker has an economic motivation for disseminating the speech. *Bolger*, at 66. If ***all three factors*** are present, the speech may properly be characterized as commercial speech. *Id.*; *see, also, Washington Legal Foundation v. Friedman*, 13 F.Supp.2d 51, 64 (D.D.C. 1998) ("*WLF I*"), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000).

On a common sense level, a more robust warning of the risks of an approved drug does not comport with

the *Bolger* test for commercial speech. After all, an advertisement "calls public attention to [the product], especially by emphasizing desirable qualities so as to arouse desire to buy or patronize." *WLF I*, 13 F.Supp.2d at 64. A warning about the excessive risks in using an approved drug in a particular manner does exactly the opposite: It ***de***emphasizes the desirable qualities of the drug and is necessarily intended to suppress the use of the drug. Similarly, a warning that highlights the risk of using a drug is an economic ***dis***incentive, and does not comport with the third Bolger factor because there is no economic motivation for disseminating the speech.

Because more robust warnings about the use of an approved drug are "pure" (as opposed to "commercial") speech, any content-based restriction is subject to the strict scrutiny standard. *Sable Communications of California, Inc. v. F.C.C.*, 492 U.S. 115, 126, 109 S.Ct. 2829, 106 L.Ed.2d 93; *Playboy, supra*, 529 U.S. at 813-814. Where a statute regulates speech based on content, the statute "must be narrowly tailored to promote a compelling government interest." *Playboy*, at 813. Moreover, to the extent Wyeth argues that it could not disseminate more robust and truthful warnings about the use of its product ***without prior FDA approval*** because of FDA labeling requirements, such a limitation would amount to a "prior restraint" on protected expression – which is the most serious and least tolerable infringement on First Amendment rights. *See, Organization for a Better Austin v. Keefe*, 402 U.S. 415, 419, 91 S.Ct. 1575, 29 L.Ed.2d 1 (1971); *see also, The Florida Star v. B.J.F.*, 491 U.S. 524, 533, 109 S.Ct. 2603, 105 L.Ed.2d 443 (1989).

It would be irrational to conclude that the FDA has a compelling governmental interest in keeping physicians and patients in the dark about the risks associated with the drugs they are using. Such a conclusion would, in fact, be directly contrary to the FDA's mandate that it promote and enhance consumer ***safety***. *United States v. Dotterwiech*, 320 U.S. 277, 282, 64 S.Ct. 134, 88 L.Ed. 48 (1943); see also *Cartwright v. Pfizer, Inc.*, 369 F.Supp.2d 876, 886 (E.D. Tex. 2005); *Witczak v. Pfizer, Inc.*, 377 F.Supp.2d 726, 732 (D. Minn. 2005) ("The primary purpose of both the FDCA and FDA's regulatory scheme is to protect the public.") The First Amendment assures that truthful speech that makes the use of drugs ***safer*** cannot be limited by the FDA's regulatory scheme.

To hold that Wyeth was prohibited from issuing truthful information regarding safety risks essentially concludes that the public should be kept in the dark regarding information that impacts their health and safety and that such information cannot be disclosed until the government (through the FDA) has had an opportunity to authorize or bless the message. This kind of content-based restriction on information is the type of evil the First Amendment was meant to safeguard against. *Washington Legal Foundation v. Henney*, 56 F.Supp.2d 81, 85 (D.D.C.,1999) ("*WLF III*") ("The First Amendment is premised upon the idea that people do not need the government's permission to engage in truthful, nonmisleading speech about lawful activity.") As such, a strict scrutiny analysis belies Wyeth's argument that it could not provide more robust warnings about the use of Phenergan as an IV push.

(2) Even If It Were Deemed Commercial Speech, Wyeth Has A First Amendment Right To Issue Truthful Warnings.

Even if additional warnings are deemed "commercial speech," Wyeth has a First Amendment right to issue *truthful* warnings and to publish *truthful* facts about its drug and the risks of using it. *Thompson v. Western States Medical Center*, 535 U.S. 357, 365, 122 S.Ct. 1497 (2002). In *Western States*, this Court struck down a ban on advertising unapproved compounded drugs in the FDA Modernization Act of 1997 (FDAMA). The Court applied the commercial speech test of *Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n*, 447 U.S. 557 (1980). Thus, this Court asked: (1) whether the speech was untruthful or misleading, or concerned unlawful activity (characteristics that would strip the speech of First Amendment protection and end the analysis); (2) whether the Government had asserted a "substantial" interest in restricting the speech; (3) whether the Government had demonstrated that the restriction "directly advanced" such a substantial interest; and (4) whether the Government had established that the restriction was "not more extensive than is necessary to serve that interest." *Western States*, 535 U.S. at 365.[2]

[2] This Court also clarified some ambiguities in past cases concerning the "final prong" of the commercial speech analysis, holding that "if the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so." *Id.*, at 1506. This Court emphasized that "[i]f the First Amendment means anything, it means that regulating speech must be a last -- not first — resort." *Id.*, at 1507.

a. Issuing Warnings Is Neither Unlawful Nor Inherently Misleading

As factually determined by the jury in this case, truthful additional warnings about the use of Phenergan were necessary for the protection of the plaintiff's health and safety. Wyeth has argued that it could not issue such warnings without first obtaining the FDA's approval, essentially contending that only the FDA can determine if the warning is *truthful*. Wyeth's principal brief, pp 40-45. But numerous cases have explicitly rejected the proposition that speech is "inherently misleading" because it does not satisfy government requirements.

In *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir.), *reh'g denied*, 172 F.3d 72 (D.C. Cir. 1999), the FDA contended that the health claims appellants wished to include on dietary supplements were inherently misleading because they did not meet FDA's requirement that there be "significant scientific agreement" about such claims before they could be included in the labeling for dietary supplements. The appellate court disagreed, finding the argument that health claims were inherently misleading unless they satisfied FDA's significant scientific agreement requirement "almost frivolous." 164 F.3d at 655. The court even concluded that the claims at issue had the potential to mislead, but that FDA failed to prove that the problem could not be cured through disclosures rather than an outright ban on the claims. *Id.* at 655-60.

In the context of prescription drugs, the theory that statements lacking FDA approval were inherently misleading was considered and rejected in *WLF I*.

There, the FDA argued that manufacturer-funded or manufacturer-disseminated speech about off-label uses is inherently misleading because the FDCA "prescribes a specific system for determining the 'truth' of claims about drugs and devices." *WLF I*, 13 F. Supp.2d at 67. The court concluded that FDA had no power to impose a "specific system for determining truth," holding that:

> In asserting that any and all scientific claims about the safety, effectiveness, contraindications, side effects and the like regarding prescription drugs are presumptively untruthful or misleading until the FDA has had the opportunity to evaluate them, FDA exaggerates its overall place in the universe.

Id.

The *WLF I* court went on to hold that scientific conclusion are "*not untruthful or inherently misleading merely because the FDA has not yet had the opportunity to evaluate the claim. Id.* Cases decided outside of the FDA context have reached the same conclusions about the government's power to dictate truth. In *Bioganic Safety Brands, Inc. v. Ament*, 174 F. Supp.2d 1168 (D. Colo. 2001), for example, the State of Colorado argued that safety claims about pesticides were inherently misleading because a Colorado statute banned such claims. The court found otherwise, rejecting the theory that the State could properly

determine that safety claims on pesticide labels were inherently misleading as a matter of law":

> Whether speech is "inherently misleading" . . . is a determination for the court, not the legislature, to make. If a legislature could place speech outside First Amendment protection by simply declaring the speech "inherently misleading," the First Amendment . . . would be subject to *de facto* modification by state legislatures.

Id. at 1180.[3]

In short, Wyeth cannot sustain a position that truthful warnings regarding the danger of using Phenergan in an "IV push" context is inherently

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[3] For additional cases, *see, e.g.*, *Peel v. Attorney Reg. & Disciplinary Commission*, 496 U.S. 91, 108, 110 S.Ct. 2281, 110 L.Ed.2d 83 (1990) ("[w]hether the inherent character of a statement places it beyond the protection of the First Amendment is a question of law over which Members of this Court should exercise *de novo* review"); *Nutritional Health Alliance v. Shalala*, *953* F. Supp. 526, 529 (S.D.N.Y. 1997), *aff'd in part, vacated and dismissed in part on other grounds*, 144 F.3d 220 (2d Cir. 1998) ("[a]lthough the Government argues that health claims that have not been FDA approved are inherently misleading, not all potential health claims are misleading; at least some can be presented in a non-misleading fashion"); *Ass'n of Nat'l Advertisers, Inc. v. Lungren*, 809 F. Supp. 747, 756 (N.D. Cal. 1992), *aff'd*, 44 F.3d 726 (9th Cir. 1994) ("[i]f First Amendment scrutiny in the commercial speech arena is to have any bite at all, a legislative body cannot justify its restrictions on commercial speech simply by declaring that marketing claims are misleading").

misleading unless it complies with FDA requirements. Such a position would nullify the constitutional protections accorded to commercial speech, and the cases have squarely rejected this sort of "*de facto* modification" of the First Amendment. Simply put, government-mandated systems for determining truth are not a part of our First Amendment jurisprudence.

b. While the FDA May Have A "Substantial Interest" In Protecting The Health and Safety of Citizens, It Cannot Restrict Truthful Information Out of Fear That it May be Misused

It is not disputed that government agencies may seek to regulate speech for certain legitimate purposes — perhaps most importantly in the FDA context, to prevent the serious harms that can result from *untruthful* speech. Whether speech is categorized as commercial or non-commercial, a restriction designed to prevent citizens from using ***truthful*** information to make choices about lawful activities does not satisfy this requirement. The First Amendment "directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503, 116 S.Ct. 1495, 134 L.Ed.2d 711 (1996).

This principle has been recognized repeatedly in cases involving restrictions on information about drugs and devices, including this Court's first decision extending First Amendment protection to commercial

speech. In that case, *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 769, 96 S.Ct. 1817, 48 L.Ed.2d 346 (1976), the State of Virginia argued that a ban on advertising prescription drug prices was justified by the fear "that if the pharmacist who wishes to provide low cost, and assertedly low quality, services is permitted to advertise, he will be taken up on his offer by too many unwitting customers." This Court disagreed, holding at 770 that:

> Virginia is free to require whatever professional standards it wishes of its pharmacists. . . . But it may not do so by keeping the public in ignorance of the entirely lawful terms that competing pharmacists are offering. . . . [T]he justifications Virginia has offered for suppressing the flow of prescription drug price information, far from persuading us that the flow is not protected by the First Amendment, have reinforced our view that it is. We so hold.

Similarly, the court in *WLF I* rejected paternalism as a valid basis for restricting the dissemination of truthful information about off-label uses of drugs and devices, holding that "[t]o the extent that the FDA is endeavoring to keep information from physicians out of concern that they will misuse that information, the regulation is wholly and completely insupportable." *WLF I*, 13 F. Supp.2d at 69. "If there is one fixed principle in the commercial speech arena," the court observed, "it is that 'a State's paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to

suppress it.'" *Id.* at 69-70 *quoting 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 497 (1996).[4]

In *Western States*, this Court rejected the theory that an interest in protecting patients from truthful information could justify its suppression. There, the Court addressed the argument that FDAMA's ban on advertising compounded drugs could be sustained by an interest in preventing patients who do not need compounded drugs from seeking them, holding that:

> Even if . . . FDAMA's speech-related restrictions were motivated by a fear that advertising compounded drugs would put people who do not need such drugs at risk by causing them to convince their doctors to prescribe the drugs anyway, that fear would fail to justify the restrictions. Aside from the fact that this concern rests on the questionable assumption that doctors would prescribe unnecessary medications . . . [it] amounts to a fear that people would make bad decisions if given truthful information about compounded drugs. . . . We have previously rejected the notion that the Government has an interest in preventing the dissemination

[4] This analysis, of course, wholly undermines Wyeth's argument that the FDA's approval process must be upheld in order to avoid "over warning," i.e., giving so many warnings that physicians will simply ignore ***all*** the warnings. That "paternalistic assumption" that physicians will not heed the warnings if too many are given "cannot justify a decision" to suppress truthful warnings.

> of truthful commercial information in order to prevent members of the public from making bad decisions with the information.

Western States, 535 U.S. at 374.

Other courts have similarly held that "[t]he First Amendment mandates that we presume that speakers, not the government, know best both what they want to say and how to say it." *Riley v. Nat'l Fed'n of Blind, Inc.*, 487 U.S. 781, 790 91, 108 S.Ct. 2667, 101 L.Ed.2d 669 (1988). In fact, "[t]he very purpose of the First Amendment is to foreclose public authority from assuming a guardianship of the public mind through regulating the press, speech, and religion." *Thomas v. Collins*, 323 U.S. 516, 545, 65 S.Ct. 315, 89 L.Ed. 430 (1945) (Jackson, J., concurring). "To this end, the government, even with the purest of motives, may not substitute its judgment as to how best to speak for that of speakers and listeners; free and robust debate cannot thrive if directed by the government." *Riley*, 487 U.S. at 791. Accordingly, in light of the foregoing authority, the FDA could not prevent Wyeth from issuing truthful warnings regarding the use of Phenergan in an "IV push" mode.

c. The Purported Restrictions on Speech Do Not Advance the Government's Substantial Interest in Protecting the Health and Safety of Consumers

This Court has repeatedly confirmed that the role of the FDCA and the FDA is to protect consumers. *F.D.A. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000) ("The labeling requirements currently imposed by the FDCA . . . require the FDA to regulate the labeling of drugs and devices to protect the safety of consumers."); *United States v. Sullivan*, 332 U.S. 689, 696, 68 S.Ct. 331, 92 L.Ed. 297 (1948) ("[T]he Act as a whole was ***designed primarily to protect consumers from dangerous products***." [Emphasis added].).

This intent is also reflected in the FDA's regulations. Prior to 1965, the FDA expressly prohibited drug companies from strengthening the warnings in their drug labels without ***prior*** FDA approval. 25 Fed.Reg. 12,592, 12,595 (Dec. 9, 1960.) In 1965, however, the FDA recognized the importance of incentivizing drug companies to warn of additional risks when appropriate, and to do so without the FDA's pre-approval. 30 Fed.Reg. 993 (Jan. 30, 1965).

In light of the fact that the FDCA's primary objective is to protect consumers, that objective and interest would not be advanced by accepting Wyeth's contention that the FDA could or should prohibit a ***truthful*** warning about the use of its product. *See, e.g., United States v. Dotterweich*, 320 U.S. 277, 282 (1943);

see also Cartwright, 369 F.Supp.2d at 886; *Witczak*, *supra*, 377 F.Supp.2d at 732. The more information a physician has when prescribing a drug, the better. *See*, American Medical Association, *Reporting Adverse Drug and Medical Device Events: Report of the AMA's Council on Ethical and Judicial Affairs*, 49 Food & Drug Law Journal 359, 363 (1994) ("The purpose of any requirement to disseminate knowledge is to benefit patients and advance their level of care."). Even Professor Hall, a spokesperson for the Washington Legal Foundation, acknowledges that "[b]etter information provided faster to patients and physicians will presumably lead to better healthcare decisions." Ralph F. Hall, *The Risk of Risk Reduction: Can Postmarket Surveillance Pose More Risk Than Benefit?*, 62 Food & Drug L.J. 473, 479 (2007). An FDA restriction limiting the distribution of truthful warnings would undermine FDA's interest in promoting access to reliable scientific and medical information and would thereby endanger the lives of patients who are prescribed medications.

This Court's First Amendment jurisprudence has long mandated that government cannot suppress truthful information that would aid consumers — even when that information does nothing more than allow them to make better ***financial*** judgments about what they buy. *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 96 S.Ct. 1817, 48 L.Ed.2d 346 (1976); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 116 S.Ct. 1495, 134 L.Ed.2d 711 (1996); *Thompson v. Western States Medical Center*, 535 U.S. 357, 365, 122 S.Ct. 1497 (2002). It is far more important that these First Amendment principles apply

to assure that patients and their physicians have truthful information that will assist them in choosing drug products that affect consumers' health and safety and not merely their pocketbooks. An FDA regulation that limits the dissemination of truthful warnings undermines patient safety, is contrary to governmental intent and violates the First Amendment.

d. A Restriction On Warnings Is More Extensive than Necessary

Finally as to the fourth factor, Wyeth's contention that the FDA does or should bar all additional warnings until approved by the FDA is more extensive than necessary since it burdens substantially more speech than necessary. *U.S. v. Edge Broadcasting Co.*, 509 U.S. 418, 430, 113 S.Ct. 2696, 125 L.Ed.2d 345 (1993). First, as already noted, such a restriction would be an unnecessary and unconstitutional prior restraint. *See, e.g., WLF II*, 56 F.Supp.2d at 85. Second, as the *WLF I* court noted, in lieu of prohibiting speech, the FDA could require "full, complete, and unambiguous disclosure by the manufacturer." *WLF I*, 13 F.Supp.2d at 73. Finally, as the *WLF I* court noted, the FDA cannot restrict the dissemination of truthful information, especially when the "truthful information may be life saving information." *WLF I*, 13 F.Supp.2d at 73. Truthful warnings are exactly the type of life-saving information that cannot be restricted and is fully protected by the First Amendment.

The FDA has long understood that completely suppressing the exchange of accurate scientific and medical information between physicians and the

manufacturers of drugs and devices does not serve its public health objectives. For example, the FDA stated in 1994 that, "because the agency recognizes the importance of dissemination of reliable scientific information . . . , it has developed a number of policies related to dissemination of such information." 59 Fed. Reg. 59820, 59822 (Nov. 18, 1994). In its most recent pronouncement on this issue, the FDA confirmed that manufacturers have a right to "disseminate truthful and non misleading medical journal articles and medical or scientific reference publications on unapproved uses of approved drugs...to healthcare professionals." *See* FDA Guidance for Industry, available at *http://www.fda.gov/oc/op/ goodreprint.html*, at p. 3. The FDA further held that, along with the dissemination of such information, the manufacturer should also disclose "***any significant risks or safety concerns known to the manufacturer*** . . ." *See id.*, at p. 6. Thus, contrary to Wyeth's contention, Wyeth was not only permitted but ***encouraged*** to disclose any known safety problems with its drug. For this reason alone, Wyeth's preemption argument should be rejected.

Accordingly, under the First Amendment, Wyeth had a right to issue truthful additional warnings about the risks of using Phenergan in an IV push.

(3) As the industry itself vociferously argues, the First Amendment permits drug manufacturers to provide truthful information about their products in addition to the FDA-approved drug label.

As Professor Ralph F. Hall, writing for the Washington Legal Foundation, stated in December 2005, "[f]or more than a decade, the pharmaceutical industry, the Food and Drug Administration ("FDA") and the courts have struggled to integrate FDA's regulation of off-label promotion of drugs [fn omitted] with the First Amendment's protection of free speech." WLF, "Legal Backgrounder," Vol. 20, No. 59, December 2, 2005, available at *www.wlf.org/upload/120205LBHall.pdf*, most recently accessed on 8/11/08. The Washington Legal Foundation has been very active on behalf of the industry in convincing courts that the FDA's power over the contents of a drug's label does not impair a drug company's right to promote its products' off-label use through the publication and dissemination of scientific articles. *See, e.g., WLF I*; *WLF II*; *WLF II*); *Washington Legal Foundation v. Henney*, 128 F.Supp.2d 11 ("*WLF V*"). In the *Freidman* litigation, the Washington Legal Foundation actually obtained a permanent injunction against the FDA to stop it from initiating enforcement actions against drug makers who provided truthful scientific studies to physicians about their drugs' off-label uses. The FDA's appeal of that injunction was dismissed as "moot" because the FDA agreed that the First Amendment precluded such enforcement actions. *Washington Legal Foundation v. Friedman*, 202 F.3d 331, 335-337 (D.C. Cir. 2000) ("*WLF IV*").

As recently as April 21, 2008, the Washington Legal Foundation concluded that this series of cases stand for the proposition that the FDA cannot regulate truthful statements by a drug company about its products, in whatever venue or context, and that the FDA's proposed regulatory guidance on off-label communications with physicians not only violates the injunction issued against the FDA on these issues, but generally violates the First Amendment as well. *See Comments of The Washington Legal Foundation to the Food and Drug Administration Department of Health & Human Services Concerning Draft Guidance for Industry on Good Reprint Practices in Response to the Public Notice Published at 73 Fed. Reg. 9342 (February 20, 2008)*, dated April 21, 2008, pp 11-17, available at *http://www.wlf.org/upload/Reprints%20Guidance-%20WLF%20Comments.pdf*, last accessed on 8/9/08. ("Comments.")

Washington Legal Foundation's focus in its litigation against the FDA and in its Comments is the First Amendment right of drug manufacturers to disseminate scientific studies supporting the use of an FDA-approved drug for treatment of a condition for which the drug has not yet been approved by the FDA. But as Professor Hall explains, "[o]ff-label speech involves ***any*** discussion about a product's uses, ***safety***, or efficacy that is outside of the FDA-approved labeling." (*Id.*, at p. 2; emphasis added.) Thus, the WLF's arguments that the First Amendment precludes the FDA's regulation of a manufacturer's dissemination of truthful information about its drugs applies with equal force irrespective of whether the information relates to additional uses for the drug ("off-label" uses) or more robust warnings about risks associated with the use of the drug.

This was also recently the conclusion of Daniel Troy, the Chief Counsel to the FDA from 2001-2004, in a published response in the New England Journal of Medicine to a prior article advocating for limits on the promotion of off-label uses of approved drugs. As Mr. Troy stated, that article "dramatically understate[d] the robust, sound constitutional protection the U.S. Supreme Court affords truthful, nonmisleading commercial communication such as that embodied in reprints of scientific articles discussing off-label uses." *New England Journal of Medicine*, July 31, 2008, p. 536. Further, Mr. Troy stated, "[a]ppropriate off-label use that informs proper patient care is fostered by more, not less, communication of truthful, nonmisleading information." *Id.*

Thus, as the industry itself argues, dissemination of truthful, nonmisleading warnings that are not otherwise contained in the FDA-approved drug label is speech protected by the First Amendment.[5]

[5] The truth of scientific information about the risks associated with drugs naturally would be tested as those products enter the marketplace and are used by consumers. If, as a result, the public begins to doubt the completeness and accuracy of manufacturers' statements about drug risk, individuals would be able to seek accurate information through state product liability actions. Recourse to the courts increases the incentives for manufacturers to disclose truthful information, informs the public of any previously undisclosed risks, and helps cure deficiencies in the FDA's approval and post-marketing review process.

B. To avoid constitutional doubts, the statute and regulation should be interpreted to allow drug companies to issue additional warnings.

Statutes, and the regulations drafted pursuant to them, must be interpreted so as to avoid constitutional doubts. *Miller v. French*, 530 U.S. 327, 336, 120 S.Ct. 2246, 147 L.Ed.2d 326 (2000); *Almendarez-Torres v. U.S.*, 523 U.S. 224, 237-238 118 S.Ct. 1219, 140 L.Ed.2d 350 (1998); *Communications Workers of America v. Beck*, 487 U.S. 735, 761-762, 108 S.Ct. 2641, 101 L.Ed.2d 634. Drug manufacturers have recently argued that while 21 C.F.R. section 314.70 allows them to add or strengthen a warning without prior FDA approval, they may only utilize that regulation when the additional warning is based on "newly discovered" evidence. In other words, the industry argues, if they have long known about the problem, section 314.70(c) does not permit them to issue a different warning, absent FDA approval.

First, the plain text of the regulation in no way supports that argument. On its face, section 314.70(c)(6)(iii)(A) permits a drug manufacturer to "add or strengthen a contraindication, warning, precaution, or adverse reaction" at any time. The regulation only requires that the FDA have *received* — not ruled on — a proposed supplemental change to the label. There is nothing in the text of the section that supports the conclusion that there must be "newly discovered" evidence supporting the change.

More importantly, construing the regulation in that manner violates the rule that a regulation must be

construed in a manner that resolves any doubt ***against*** unconstitutionality. Construction of the regulation in the manner suggested by the industry raises constitutional concerns to the extent it would prohibit dissemination of truthful information of hazards that have long been known, but secreted by the manufacturer for whatever reason. Such a construction of the regulation would be invalid under the First Amendment.

C. Because Wyeth had a First Amendment right to issue more robust warnings about its product than those contained in the FDA-approved label, it could comply with state law requiring those more robust warnings.

Wyeth's challenge to the Vermont Supreme Court's decision is predicated solely on principles of conflict preemption. Wyeth asserts that it could not comply with both federal law (which, Wyeth contends, precluded more robust warnings) and state law (which required more robust warnings).

But, as demonstrated, the First Amendment provided Wyeth with the right and power to disseminate truthful warnings about the use of its drug that were more robust than those contained in the FDA-approved label, regardless of whether it chose to exercise that power. Because federal law did not restrict the warnings Wyeth could issue, Wyeth could have complied with state law and issued more warnings, had it chosen to do so. There was no conflict and, hence, no conflict preemption.

It is anticipated that Wyeth will argue in response to this brief that even if the First Amendment ***allowed***

Wyeth to issue additional warnings about its drug, the First Amendment also allows it to remain silent. The problem with that argument, however, is that it ignores the context: This brief is in response to Wyeth's assertion that it ***couldn't*** legally issue additional warnings without the FDA's approval. But the First Amendment says it could. It is not the First Amendment that ***requires*** Wyeth to issue further warnings. It only ***permits*** it to do so. It is state law which imposes the duty. The point is that the state law duty is not in conflict with any federal limitation because, in fact, there is no federal limitation.

The question is this: Can a manufacturer with knowledge of a grave risk associated with its drug issue a warning to the medical community regarding that risk? Wyeth claims that federal law prohibits it from issuing such a warning. Wyeth is wrong. Wyeth was aware of the substantial risks of using Phenergan in an IV push mode. Wyeth had both a state law duty and a First Amendment right to issue a warning regarding that risk without waiting for the FDA's confirmation of the appropriateness of the warning. Wyeth was not put to the test of choosing between compliance with state law requiring the warning and federal law precluding the warning, because the federal regulations purportedly precluding the warning violated Wyeth's First Amendment right to give it. Wyeth could, therefore, comply with both federal and state law.

CONCLUSION

First Amendment jurisprudence requires rejection of Wyeth's argument that it could not issue additional truthful warnings about its product.

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